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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,984	07/24/2003	Jungwon Shin	INL-059	1711

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EXAMINER	
NOGUEROLA, ALEXANDER STEPHAN	
ART UNIT	**PAPER NUMBER**
1753	

MAIL DATE	DELIVERY MODE
06/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/625,984	SHIN ET AL.	
	Examiner	Art Unit	
	ALEX NOGUEROLA	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,17,19,20,22-26,36,38-42,45, 46, 54* is/are rejected.

7)☒ Claim(s) *5,8-16,18,21,27-35,37,43,44,47-53 and 55* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Oath/Declaration

1. The Declaration under 37 CFR 1.131 filed June 06, 2007 is sufficient to overcome the rejection of claims 1-55 based upon Mansouri.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1, 2, 3, 5-7, 19, 20, 22, 24-26, 39-42, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doretti et al. ("Covalently immobilized enzymes on biocompatible polymers for amperometric sensor applications," Biosensors and Bioelectronics Vol. 11, No. 4, pp. 365-373, 1996) ("Doretti") in view of "Water on the Web: The Chemistry of Oxygen Solubility Reading" ("Water Web").

Addressing claims 1, 19, 20, and 38 Doretti discloses a solution for the calibration of sensor, the solution comprising a selected concentration of choline (implied by Figure 7, which shows a Hanes plot of calibration data for a choline electrode and the first paragraph of Experimental – Materials on page 366, which discloses stock choline solutions).

Doretti does not mention whether the oxygen content of the calibration solution is known. However, it would have been obvious to one with ordinary skill in the art at the

time of the invention to determine the oxygen content because it was known at the time of the invention that water exposed to the atmosphere will have an oxygen content (Water Web) and although the sensor of Doretti is a choline sensor the electrode is an oxygen sensor that measures oxgen decrease due to enzymatic reaction. See the abstract and the first paragraph of Electrochemical measurements on page 368. So one with ordinary skill in the art at the time of the invention would want to know the oxygen content of the calibration solution as this should be a controlled background signal to avoid making the measurement value for choline larger that it should be.

Doretti also does not mention whether the selected concentration of choline is sufficient to reduce a rate of low of oxygen content in the solution; however, Applicant has found that choline *inherently* reduces the loss of oxygen content when in a solution containing oxygen. See, for example, the last paragraph on page 14, bridging to page 15 of the specification, which is only cited to show a property of choline.

As for the known oxygen content in the solution being sufficient for calibration of the oxygen sensor, although Doretti uses the solution(s) for calibrating a choline sensor since they inherently have an oxygen content and the type and sensitivity of the claimed oxygen sensor is not limited the solution(s) could be used to calibrate an oxygen sensor.

For claims 19 and 20 note that is was common at the time of the invention to store solutions in a container, particularly a gas-impermeable container, such as a vial, beaker, pouch.

For claim 38 note that since choline inherently reduces the rate of loss of oxygen content in a solution, whoever prepared the choline stock solutions and calibration solutions reduced the rate of loss of the oxygen inherently in the solution.

Addressing claim 2, barring a contrary showing this is an arbitrary range since the amounts of choline and oxygen are not specified. In any event it should be noted that the oxygen content of the calibration solution would be expected to be about 158 mm Hg, which is the partial pressure of oxygen in water (see Water Web). Since Doretti discloses a range of choline concentrations the oxygen loss rate can be controlled as desired.

Addressing claim 3, 22, 41, for the additional limitation of this claim see in Doretti the first paragraph of Experimental – Materials on page 366.

Addressing claims 5, 6, 24, 25, 39, and 40, for the additional limitation of this claim see in Doretti the x-axis in Figure 4.

Addressing claims 7, 26, and 42, for the additional limitation of this claim see Water Web which discloses that about 158 mm Hg is the partial pressure of oxygen in water.

Addressing claim 45, for the additional limitation of this claim see Figure 4 in Doretti.

6. Claims 1, 2, 7, 19, 20, 26, 38, 42, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable Tasset (US 4,686,002) ("Tasset") in view of "Water on the Web: The Chemistry of Oxygen Solubility Reading" ("Water Web").

Addressing claim 1, Tasset discloses a solution for the calibration of a sensor, the solution comprising a selected concentration of choline (col. 04:02-21).

Tasset does not mention whether the oxygen content of the calibration solution is known. However, it would have been obvious to one with ordinary skill in the art at the time of the invention to determine the oxygen content because it was known at the time of the invention that water exposed to the atmosphere will have an oxygen content (Water Web) and Tasset suggests using the solution in applications where oxygen can be a factor in quality control or effectiveness, such as, cleaning solutions, ethcants for semiconductors and metal layers, and developers and strippers for positive working resists. See the abstract.

Tasset also does not mention whether the selected concentration of choline is sufficient to reduce a rate of low of oxygen content in the solution; however, Applicant have found that choline *inherently* reduces the loss of oxygen content when in a solution

containing oxygen. See, for example, the last paragraph on page 14, bridging to page 15 of the specification, which is only cited to show a property of choline.

As for the known oxygen content in the solution being sufficient for calibration of the oxygen sensor, this is only an intended use for which the solution(s) of Tasset is capable since it inherently has an oxygen content and the type and sensitivity of the claimed oxygen sensor is not limited.

For claims 19 and 20 note that is was common at the time of the invention to store solutions in a container, particularly a gas-impermeable container, such as a vial, beaker, or pouch.

For claim 38 note that since choline inherently reduces the rate of loss of oxygen content in a solution, whoever prepared the choline stock solutions and calibration solutions reduced the rate of loss of the oxygen inherently in the solution.

Addressing claim 2, barring a contrary showing this is an arbitrary range since the amounts of choline and oxygen are not specified. In any event it should be noted that the oxygen content of the calibration solution would be expected to be about 158 mm Hg, which is the partial pressure of oxygen in water (see Water Web). Since Tasset discloses a range of choline concentrations the oxygen loss rate can be controlled as desired.

Addressing claims 7, 26, and 42, for the additional limitation of this claim see Water Web which discloses that about 158 mm Hg is the partial pressure of oxygen in water.

Addressing claims 45, for the additional limitation of this claim note that Tasset discloses stabilized choline solutions of known concentration. Thus they could be used as calibration solutions.

7. Claims 1-7, 17, 19, 20, 22-26, 36, 38-42, 45, 46, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable Heinsohn et al. (US 5,209,858) ("Heinsohn") in view of "Water on the Web: The Chemistry of Oxygen Solubility Reading" ("Water Web").

Addressing claim 1, Heinsohn discloses a solution for the calibration of a sensor, the solution comprising a selected concentration of choline (abstract and col. 02:13-31).

Heinsohn does not mention whether the oxygen content of the calibration solution is known. However, it would have been obvious to one with ordinary skill in the art at the time of the invention to determine the oxygen content because it was known at

the time of the invention that water exposed to the atmosphere will have an oxygen content (Water Web) and Heinshohn suggests using the solution in applications where oxygen can be a factor in quality control or effectiveness, such as, a nutritional substance for treating liver disorders, in animal feed, as a photoresist stripper, and cleaning silicon wafers. See col. 01:24-31.

Heinsohn also does not mention whether the selected concentration of choline is sufficient to reduce a rate of low of oxygen content in the solution; however, Applicant have found that choline *inherently* reduces the loss of oxygen content when in a solution containing oxygen. See, for example, the last paragraph on page 14, bridging to page 15 of the specification, which is only cited to show a property of choline.

As for the known oxygen content in the solution being sufficient for calibration of the oxygen sensor, this is only an intended use for which the solution(s) of Heinsohn is capable since it inherently has an oxygen content and the type and sensitivity of the claimed oxygen sensor is not limited.

For claims 19 and 20 note that is was common at the time of the invention to store solutions in a container, particularly a gas-impermeable container, such as a vial, beaker, or pouch.

For claim 38 note that since choline inherently reduces the rate of loss of oxygen content in a solution, whoever prepared the choline stock solutions and calibration solutions reduced the rate of loss of the oxygen inherently in the solution.

Addressing claim 2 , barring a contrary showing this is an arbitrary range since the amounts of choline and oxygen are not specified. In any event it should be noted that the oxygen content of the calibration solution would be expected to be about 158 mm Hg, which is the partial pressure of oxygen in water (see Water Web). Since Tasset discloses a range of choline concentrations the oxygen loss rate can be controlled as desired.

Addressing claims 3, 4, 22, 23, 41, and 46, for the additional limitations of these claims see in Heinsohn col. 01:32-40.

Addressing claims 5, 6, 24, 25, 39, and 40 for the additional limitation of this claim note that Heinshon discloses a choline range of 0.1wt% - 50% or higher. See col. 02:22-24. Also note that 20mml/L choline is 0.28wt%.

Addressing claims 7, 26, and 42, for the additional limitation of this claim see Water Web which discloses that about 158 mm Hg is the partial pressure of oxygen in water.

Addressing claims 17, 36, and 54, for the additional limitation of this claim see the abstract.

Addressing claims 45, for the additional limitation of this claim note that Heinshon discloses choline solutions of known concentration. Thus they could be used as calibration solutions.

Allowable Subject Matter

8. Claims 8-16, 18, 21, 27, 28-35, 37, 43, 44, 47-53, and 55 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. The following is a statement of reasons for the indication of allowable subject matter:

a) Claims 8, 27, and 43: each combination of limitations require the oxygen content to be about 100 mm Hg. In Doretti, Tasset, and Heinshon the oxygen content would be expected to be about 158 mmHg, which is the partial pressure of oxygen in water at sea level.

a) Claims 9, 28, and 44: the combination of limitations require the oxygen content

to be about 180 mm Hg. In Doretti, Tasset, and Heinshon the oxygen content would be expected to be about 158 mmHg, which is the partial pressure of oxygen in water at sea level.

b) Claims 10-16, 18, 29-35, 37, 47-53, and 55: each combination of limitations requires an additional ingredient that would not be expected in the solutions of Doretti, Tasset, and Heinshon except in trace amounts.

c) Claim 21: the combination of limitations requires the container to be sealed to prevent a headspace comprising a gas.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alex Noguerola
Primary Examiner
AU 1753
June 24, 2007